



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1100, 1107, and 1114

[Docket No. FDA-2019-N-2854]

RIN 0910-AH44

Premarket Tobacco Product Applications and Recordkeeping Requirements; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period only for the agency information collection activity associated with proposed rulemaking entitled "Premarket Tobacco Product Applications and Recordkeeping Requirements", which appeared in the *Federal Register* of September 25, 2019. FDA is not reopening the comment period associated with any other aspects of the proposed rulemaking. The Agency is taking this action to seek comment on an additional proposed form to collect information that would be required under certain provisions of the proposed rule. This proposed form would allow for easier identification of each new tobacco product contained in a grouped submission of premarket tobacco product applications (PMTAs). FDA is reopening the comment period only on the proposed agency information collection activity to allow interested persons additional time to submit comments on this form.

DATES: FDA is reopening the comment period on the agency information collection activity contained in the proposed rule published in the *Federal Register* of September 25, 2019 (84 FR

50566). Submit either electronic or written comments by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0879 and title "Premarket Tobacco Product Applications and Recordkeeping Requirements." Also include the FDA docket number found in brackets in the heading of this document.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of September 25, 2019 (84 FR 50566), FDA published a proposed rule that included an agency information collection assessment with a 60-day comment period to request comments on proposed requirements related to PMTA reporting and recordkeeping. In the *Federal Register* of November 26, 2019 (84 FR 65044), FDA published a document reopening the comment period on the proposed rule

for an additional 20 days in response to multiple requests from commenters and the comment period closed on December 16, 2019.

FDA is reopening the comment period for the agency information collection activity associated with the proposed rulemaking for a period of 30 days, until [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], to allow comment on an additional proposed form. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking.

FDA has included an additional proposed form (Form FDA 4057b) in the docket that will assist industry and FDA in identifying the products that are the subject of a submission where an applicant groups multiple PMTAs into a single submission (referred to as a bundled submission or a grouped submission). FDA has previously stated that one approach to submitting PMTAs could be to group applications for products that are both from the same manufacturer or domestic importer and in the same product category and subcategory into a single submission. FDA discusses bundled submissions in the proposed rule (84 FR 50566 at 50578) and notes that FDA intends to consider information on each tobacco product as a separate, individual PMTA. The form would assist applicants in providing the unique identifying information for each product in a grouped submission of PMTAs that would be required by table 1 to 21 CFR 114.7(c)(3)(iii) of the proposed rule (84 FR 50566 at 50637). By having the identifying information for products contained in a submission be more clearly organized, FDA will be able to more efficiently process and review the applications contained in a grouped submission.

FDA is revising table 22 from the Paperwork Reduction Act section contained in the proposed rule (84 FR 50566 at 50627) to add the associated burden for the additional proposed form. We estimate that 24 respondents will complete Form FDA 4057b for a total of 96 hours.

Based on the Form FDA 4057 for use when submitting PMTA single and bundled submissions, FDA estimated that 24 respondents will submit PMTA bundles per year. Form FDA 4057b would be created once for each submission containing more than one PMTA. We assume the submitter could include from 2 to 2,000 products in each Form FDA 4057b. Entering data for up to 2,000 rows can take approximately 4 hours on average per Form FDA 4057b for manual data entry. If the data entry is automated, it could be performed more quickly. Assuming 4 hours per Form FDA 4057b for 24 applications, we estimate a total burden of 96 hours for this new activity. FDA does not believe the recordkeeping burden will be affected by the addition of the form.

The new total burden for the collections of information in this rulemaking are estimated to be 22,610 reporting hours and 52 recordkeeping hours for a total of 22,662 hours. In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the *Federal Register*.

Dated: March 4, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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